### Food and Drug Administration, HHS

area of response desired. An injection of 1 milliliter will produce a response of approximately 15 square centimeters. Do not inject more than 2 milliliters per injection site. Regardless of the number of injection sites, the total volume used should not exceed 10 milliliters.

- (3) Not for use in horses intended for food.
- (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 27034, July 1, 1976, as amended at 50 FR 40966, Oct. 8, 1985]

#### §522.1620 Orgotein for injection.

- (a) Specifications. Orgotein for injection is packaged in a vial containing 5 milligrams of orgotein and 10 milligrams of sucrose as lyophilized sterile nonpyrogenic powder with directions for dissolving the contents of the vial in 2 milliliters of diluent which is sodium chloride injection, U.S.P.
- (b) Sponsor. See No. 024991 in  $\S510.600(c)$  of this chapter.
- (c) Conditions of use—(1) Horses. (i) It is used in the treatment of soft tissue inflammation associated with the musculoskeletal system.
- (ii) It is administered by deep intramuscular injection at a dosage level of 5 milligrams every other day for 2 weeks and twice weekly for 2 to 3 more weeks. Severe cases, both acute and chronic, may benefit more from daily therapy initially. Dosage may be continued beyond 5 weeks if satisfactory improvement has not been achieved.
- (iii) Not for use in horses intended for food.
- (2) Dogs. (i) It is used for the relief of inflammation associated with ankylosing spondylitis, spondylosis, and disc disease. When severe nerve damage is present, response will occur much more slowly, if at all.
- (ii) It is administered by subcutaneous injection at a dosage level of 5 milligrams every day for 6 days, and thereafter, every other day for 8 days. In less severe conditions, shorter courses of therapy may be indicated.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 32583, Aug. 4, 1976]

# § 522.1642 Oxymorphone hydrochloride injection.

- (a) Specifications. The drug contains 1 or 1.5 milligrams of oxymorphone hydrochloride per milliliter of aqueous solution containing 0.8 percent sodium chloride.
- (b) Sponsor. See No. 060951 in \$510.600(c) of this chapter.
- (c) Conditions of use. (1) The drug is a narcotic analgesic, preanesthetic, anesthetic, and substitute anesthetic adjuvant for intramuscular, subcutaneous or intravenous administration to cats and dogs as follows:

Animal	Body weight (pounds)	Dosage (milligram)
Dogs	2 to 5	0.75
•	5 to 15	0.75-1.5
	15 to 30	1.5-2.5
	30 to 60	2.5-4.0
	Over 60	4.0
Cats	Small	0.4-0.75
	Large	0.75–1.5

- (2) Do not mix with a barbiturate in the same syringe to preclude precipitation.
- (3) It tends to depress respiration. Naloxone hydrochloride and other narcotic antagonists are used to counter over-dosing.
- (4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 63 FR 7701, Feb. 17, 1998]

## § 522.1660 Oxytetracycline injectable dosage forms.

### § 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.

- (a) *Specifications*. Each milliliter of sterile solution contains 200 milligrams of oxytetracycline base.
- (b) *Sponsors*. See Nos. 000010, 000069, 048164, 055529, 057561, 059130, and 061623 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.500 of this chapter.
- (d) Special considerations. When labeled for the treatment of anaplasmosis or anthrax, labeling shall